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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMARIN PHARMA, INC. and AMARIN PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. DR. REDDY'S LABORATORIES, INC., and DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. _____ Document Filed Electronically

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively, "Plaintiffs" or "Amarin"), by their attorneys, for their complaint against Dr.

Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Defendants" or "DRL") allege as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(a-c, e). This action relates to an Abbreviated New Drug Application ("ANDA") No. 205616 filed by or for the benefit of Defendants with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' VASCEPA® pharmaceutical products that are sold in the United States.

The Parties

2. Plaintiff Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 1430 Route 206, Bedminster, NJ 07921.

3. Plaintiff Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

4. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a company organized and existing under the laws of New Jersey with its principal place of business at 107 College Road East, Princeton, NJ 08540.

5. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a public limited liability company organized and existing under the laws of India and having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500 034, India.

6. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd.

7. Upon information and belief, Dr. Reddy's Laboratories, Ltd., either directly or through one or more of its wholly owned subsidiaries and/or agents, including Dr. Reddy's Laboratories, Inc., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

8. Upon information and belief, Dr. Reddy's Laboratories, Inc., with the assistance and/or at the direction of Dr. Reddy's Laboratories, Ltd., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

Jurisdiction and Venue

9. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the U.S. Code, for infringement of U.S. Patent No. 8,293,728 ("the '728 Patent"), U.S. Patent No. 8,318,715 ("the '715 Patent"), U.S. Patent No. 8,357,677 ("the '677 Patent"), U.S. Patent No. 8,367,652 ("the '652 Patent"), U.S. Patent No. 8,377,920 ("the '920 Patent"), U.S. Patent No. 8,399,446 ("the '446 Patent"), U.S. Patent No. 8,415,335 ("the '335 Patent"), U.S. Patent No. 8,426,399 ("the '399 Patent"), U.S. Patent No. 8,431,560 ("the '560 Patent"), U.S. Patent No. 8,440,650 ("the '650 Patent"), U.S. Patent No. 8,501,225 ("the '225 Patent"), U.S. Patent No. 8,518,929 ("the '929 Patent"), U.S. Patent No. 8,524,698 ("the '698 Patent"), U.S. Patent No. 8,546,372 ("the '372 Patent"), U.S. Patent No. 8,551,521 ("the '521 Patent"), and U.S. Patent No. 8,617,594 ("the '594 Patent").

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. On information and belief, Dr. Reddy's Laboratories, Inc. has previously submitted to, and purposefully availed itself of, the jurisdiction of the U.S. District Court for the District of New Jersey, including by filing suit in this Court. *See, e.g.*, *Dr. Reddy's Laboratories, Ltd., et al. v. Eli Lilly and Co.*, 09 Civ. 0192 (D.N.J. 2009); *Dr. Reddy's Laboratories, Ltd., et al. v. AstraZenea AB, et al.*, 08 Civ. 2496 (D.N.J. 2008).

12. On information and belief, Dr. Reddy's Laboratories, Ltd. has previously submitted to, and purposefully availed itself of, the jurisdiction of the U.S. District Court for the District of New Jersey, including by filing suit in this Court. *See, e.g.*, *Dr. Reddy's Laboratories, Ltd., et al. v. Eli Lilly and Co.*, 09 Civ. 0192 (D.N.J. 2009); *Dr. Reddy's Laboratories, Ltd., et al. v. AstraZenea AB, et al.*, 08 Civ. 2496 (D.N.J. 2008); *Reddy Cheminor, Inc., et al. v. Eli Lilly and Co.*, 01 Civ. 3220 (D.N.J. 2001); *Dr. Reddy's Laboratories, Ltd., et al. v. AAIPharma, Inc.*, 01 Civ. 3521 (D.N.J. 2001); *Dr. Reddy's Laboratories, Ltd., et al. v. AAIPharma, Inc.*, 01 Civ. 3522 (D.N.J. 2001).

13. On information and belief, Dr. Reddy's Laboratories, Inc. acts as Dr. Reddy's Laboratories, Ltd.'s agent in the United States in developing, manufacturing, distributing, marketing, offering to sell, and/or selling generic drug products for sale and use throughout the United States.

14. On information and belief, Defendants act in concert to develop generic products and to seek approval from the FDA to sell generic products throughout the United States, including within this judicial district.

15. On information and belief and as stated in the ANDA Notice Letter, ANDA No. 205616 was prepared and filed with the intention of seeking to market a generic version of Amarin's VASCEPA® product, including within this judicial district.

16. Upon information and belief, Dr. Reddy's Laboratories, Inc. is licensed by the New Jersey Department of Health and Senior Services to sell generic pharmaceutical products in New Jersey.

17. Upon information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., through Dr. Reddy's Laboratories, Inc., receive Medicaid reimbursements from drugs sold in New Jersey.

18. Upon information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. plan to sell a generic VASCEPA® product in New Jersey, list a generic VASCEPA® product on New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of a generic VASCEPA® product in New Jersey.

19. By virtue of, *inter alia*, Dr. Reddy's Laboratories, Inc. being incorporated in New Jersey and maintaining its principal place of business in New Jersey, this Court has general personal jurisdiction over Dr. Reddy's Laboratories, Inc.

20. On information and belief by virtue of, *inter alia*, Dr. Reddy's Laboratories, Ltd.'s relationship with Dr. Reddy's Laboratories, Inc., its designation of Lee Banks of the Princeton, New Jersey office of Dr. Reddy's Laboratories, Inc. as its agent for acceptance of service of process, and the sales-related activities of Defendants in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, this Court has general personal jurisdiction over Dr. Reddy's Laboratories, Ltd.

21. On information and belief, by virtue of at least, *inter alia*, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described

contacts, this Court has specific personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

22. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Regulatory Requirements for New and Generic Drugs

23. A person wishing to market a new drug that has not previously been approved by the U.S. Food and Drug Administration ("FDA") (a "pioneering" drug) must file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b).

24. A person wishing to market a generic copy of a drug that previously has been approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug Application ("ANDA") for a generic version of that drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

25. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application and safety and effectiveness conclusions. 21 U.S.C. § 355(j).

26. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

The Approved Drug Product

27. Amarin Pharmaceuticals Ireland Limited is the current holder of NDA No. 202057, for 1g icosapent ethyl capsules, which was first approved by FDA on July 26, 2012. Amarin Pharma, Inc. is Amarin Pharmaceuticals Ireland Limited's agent in the United States for purposes of communicating with FDA regarding NDA No. 202057. Amarin Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. market the approved drug product under the tradename VASCEPA®.

28. VASCEPA® is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. A true, correct, and complete copy of the Prescribing Information for VASCEPA® approved in NDA No. 202057 is attached as Exhibit A.

29. FDA has listed the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '225, '929, '698, '372, '521, and '594 Patents in the Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 202057.

30. Amarin Pharmaceuticals Ireland Limited is the owner of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '225, '929, '698, '372, '521, and '594 Patents.

ANDA No. 205616

31. Upon information and belief, on or before March 18, 2014, DRL submitted to FDA an ANDA (ANDA No. 205616) with paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for 1g icosapent ethyl capsules purportedly bioequivalent to VASCEPA®. The purpose of the ANDA is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic VASCEPA® product.

32. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 205616 for the generic VASCEPA® product is to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, *i.e.*, the same indication as that set forth in the approved labeling for VASCEPA®.

33. Upon information and belief, DRL sent Amarin a letter dated March 18, 2014, which was received by Amarin on March 20, 2014 (the "Notice Letter"). The Notice Letter represented that DRL had submitted to FDA an ANDA, No. 205616, with a paragraph IV certification for the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '225, '929, '698, '372, and '521 Patents. By letter dated April 8, 2014, DRL represented that DRL had submitted to FDA ANDA No. 205616 with a paragraph IV certification for the '594 Patent.

34. Upon information and belief, the purpose of the ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic version of VASCEPA® before the expiration of the patents listed in the Orange Book for NDA No. 202057. Hence, DRL's purpose in submitting ANDA No. 205616 is to market products described therein before expiration of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '225, '929, '698, '372, '521, and '594 Patents.

35. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count I: Patent Infringement of the '728 Patent

36. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 35 above.

37. United States Patent No. 8,293,728, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on October 23, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '728 Patent. A true and complete copy of the '728 Patent is attached hereto as Exhibit B.

38. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '728 Patent.

39. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

40. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '728 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '728 Patent.

41. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 205616 would actively induce and contribute to infringement of the '728 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

42. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '728 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

43. DRL gave written notice of its certification of invalidity and/or non-infringement of the '728 Patent, alleging that claims of the '728 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '728 Patent.

44. DRL has infringed the '728 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '728 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

45. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '728 Patent. Plaintiffs do not have an adequate remedy at law.

Count II: Patent Infringement of the '715 Patent

46. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 45 above.

47. United States Patent No. 8,318,715, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on November 27, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is

the owner of the '715 Patent. A true and complete copy of the '715 Patent is attached hereto as Exhibit C.

48. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '715 Patent.

49. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

50. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '715 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '715 Patent.

51. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 205616 would actively induce and contribute to infringement of the '715 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

52. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '715 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

53. DRL gave written notice of its certification of invalidity and/or non-infringement of the '715 Patent, alleging that claims of the '715 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '715 Patent.

54. DRL has infringed the '715 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '715 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

55. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '715 Patent. Plaintiffs do not have an adequate remedy at law.

Count III: Patent Infringement of the '677 Patent

56. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 55 above.

57. United States Patent No. 8,357,677, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on January 22, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '677 Patent. A true and complete copy of the '677 Patent is attached hereto as Exhibit D.

58. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '677 Patent.

59. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '677 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

60. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '677 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '677 Patent.

61. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 205616 would actively induce and contribute to infringement of the '677 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

62. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '677 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

63. DRL gave written notice of its certification of invalidity and/or non-infringement of the '677 Patent, alleging that claims of the '677 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that

DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '677 Patent.

64. DRL has infringed the '677 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '677 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '677 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

65. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '677 Patent. Plaintiffs do not have an adequate remedy at law.

Count IV: Patent Infringement of the '652 Patent

66. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 65 above.

67. United States Patent No. 8,367,652, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on February 5, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '652 Patent. A true and complete copy of the '652 Patent is attached hereto as Exhibit E.

68. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '652 Patent.

69. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '652 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

70. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '652 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '652 Patent.

71. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 205616 would actively induce and contribute to infringement of the '652 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

72. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '652 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

73. DRL gave written notice of its certification of invalidity and/or non-infringement of the '652 Patent, alleging that claims of the '652 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '652 Patent.

74. DRL has infringed the '652 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '652 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '652 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

75. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '652 Patent. Plaintiffs do not have an adequate remedy at law.

Count V: Patent Infringement of the '920 Patent

76. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 75 above.

77. United States Patent No. 8,377,920, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on February 19, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '920 Patent. A true and complete copy of the '920 Patent is attached hereto as Exhibit F.

78. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '920 Patent.

79. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

80. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '920 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '920 Patent.

81. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 205616 would actively induce and contribute to infringement of the '920 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

82. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '920 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

83. DRL gave written notice of its certification of invalidity and/or non-infringement of the '920 Patent, alleging that claims of the '920 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '920 Patent.

84. DRL has infringed the '920 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the

‘920 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the ‘920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

85. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the ‘920 Patent. Plaintiffs do not have an adequate remedy at law.

Count VI: Patent Infringement of the ’446 Patent

86. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 85 above.

87. United States Patent No. 8,399,446, entitled “METHODS OF TREATING HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and Trademark Office on March 19, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the ‘446 Patent. A true and complete copy of the ‘446 Patent is attached hereto as Exhibit G.

88. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the ‘446 Patent.

89. DRL’s manufacture, use, offer for sale, or sale of such product would infringe the claims of the ‘446 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

90. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL’s ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the

doctrine of equivalents, of one or more claims of the '446 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '446 Patent.

91. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 205616 would actively induce and contribute to infringement of the '446 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

92. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '446 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

93. DRL gave written notice of its certification of invalidity and/or non-infringement of the '446 Patent, alleging that claims of the '446 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '446 Patent.

94. DRL has infringed the '446 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '446 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '446 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

95. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '446 Patent. Plaintiffs do not have an adequate remedy at law.

Count VII: Patent Infringement of the '335 Patent

96. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 95 above.

97. United States Patent No. 8,415,335, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on April 9, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '335 Patent. A true and complete copy of the '335 Patent is attached hereto as Exhibit H.

98. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '335 Patent.

99. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

100. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '335 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement,

and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '335 Patent.

101. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 205616 would actively induce and contribute to infringement of the '335 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

102. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '335 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

103. DRL gave written notice of its certification of invalidity and/or non-infringement of the '335 Patent, alleging that claims of the '335 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '335 Patent.

104. DRL has infringed the '335 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '335 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

105. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '335 Patent. Plaintiffs do not have an adequate remedy at law.

Count VIII: Patent Infringement of the '399 Patent

106. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 105 above.

107. United States Patent No. 8,426,399, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on April 23, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '399 Patent. A true and complete copy of the '399 Patent is attached hereto as Exhibit I.

108. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '399 Patent.

109. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

110. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '399 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '399 Patent.

111. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in

ANDA No. 205616 would actively induce and contribute to infringement of the '399 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

112. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '399 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

113. DRL gave written notice of its certification of invalidity and/or non-infringement of the '399 Patent, alleging that claims of the '399 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '399 Patent.

114. DRL has infringed the '399 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '399 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

115. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '399 Patent. Plaintiffs do not have an adequate remedy at law.

Count IX: Patent Infringement of the '560 Patent

116. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 115 above.

117. United States Patent No. 8,431,560, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on April 30, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '560 Patent. A true and complete copy of the '560 Patent is attached hereto as Exhibit J.

118. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '560 Patent.

119. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '560 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

120. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '560 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '560 Patent.

121. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in

ANDA No. 205616 would actively induce and contribute to infringement of the '560 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

122. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '560 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

123. DRL gave written notice of its certification of invalidity and/or non-infringement of the '560 Patent, alleging that claims of the '560 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '560 Patent.

124. DRL has infringed the '560 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '560 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '560 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

125. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '560 Patent. Plaintiffs do not have an adequate remedy at law.

Count X: Patent Infringement of the '650 Patent

126. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 125 above.

127. United States Patent No. 8,440,650, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on May 14, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '650 Patent. A true and complete copy of the '650 Patent is attached hereto as Exhibit K.

128. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '650 Patent.

129. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

130. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '650 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '650 Patent.

131. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in

ANDA No. 205616 would actively induce and contribute to infringement of the '650 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

132. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '650 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

133. DRL gave written notice of its certification of invalidity and/or non-infringement of the '650 Patent, alleging that claims of the '650 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '650 Patent.

134. DRL has infringed the '650 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '650 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

135. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '650 Patent. Plaintiffs do not have an adequate remedy at law.

Count XI: Patent Infringement of the '225 Patent

136. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 135 above.

137. United States Patent No. 8,501,225, entitled "STABLE PHARMACEUTICAL COMPOSITION AND METHODS OF USING SAME," was duly and legally issued by the United States Patent and Trademark Office on August 6, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '225 Patent. A true and complete copy of the '225 Patent is attached hereto as Exhibit L.

138. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '225 Patent.

139. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '225 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

140. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '225 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '225 Patent.

141. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in

ANDA No. 205616 would actively induce and contribute to infringement of the '225 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

142. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '225 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

143. DRL gave written notice of its certification of invalidity and/or non-infringement of the '225 Patent, alleging that claims of the '225 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '225 Patent.

144. DRL has infringed the '225 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '225 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '225 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

145. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '225 Patent. Plaintiffs do not have an adequate remedy at law.

Count XII: Patent Infringement of the '929 Patent

146. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 145 above.

147. United States Patent No. 8,518,929, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on August 27, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '929 Patent. A true and complete copy of the '929 Patent is attached hereto as Exhibit M.

148. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '929 Patent.

149. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

150. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '929 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '929 Patent.

151. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in

ANDA No. 205616 would actively induce and contribute to infringement of the '929 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

152. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '929 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

153. DRL gave written notice of its certification of invalidity and/or non-infringement of the '929 Patent, alleging that claims of the '929 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '929 Patent.

154. DRL has infringed the '929 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '929 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

155. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '929 Patent. Plaintiffs do not have an adequate remedy at law.

Count XIII: Patent Infringement of the '698 Patent

156. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 155 above.

157. United States Patent No. 8,524,698, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on September 3, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '698 Patent. A true and complete copy of the '698 Patent is attached hereto as Exhibit N.

158. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '698 Patent.

159. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

160. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '698 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '698 Patent.

161. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in

ANDA No. 205616 would actively induce and contribute to infringement of the '698 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

162. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '698 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

163. DRL gave written notice of its certification of invalidity and/or non-infringement of the '698 Patent, alleging that claims of the '698 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '698 Patent.

164. DRL has infringed the '698 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '698 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

165. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '698 Patent. Plaintiffs do not have an adequate remedy at law.

Count XIV: Patent Infringement of the '372 Patent

166. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 165 above.

167. United States Patent No. 8,546,372, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on October 1, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '372 Patent. A true and complete copy of the '372 Patent is attached hereto as Exhibit O.

168. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '372 Patent.

169. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

170. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '372 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '372 Patent.

171. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in

ANDA No. 205616 would actively induce and contribute to infringement of the '372 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

172. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '372 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

173. DRL gave written notice of its certification of invalidity and/or non-infringement of the '372 Patent, alleging that claims of the '372 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '372 Patent.

174. DRL has infringed the '372 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '372 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

175. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '372 Patent. Plaintiffs do not have an adequate remedy at law.

Count XV: Patent Infringement of the '521 Patent

176. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 175 above.

177. United States Patent No. 8,551,521, entitled "STABLE PHARMACEUTICAL COMPOSITION AND METHODS OF USING SAME," was duly and legally issued by the United States Patent and Trademark Office on October 8, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '521 Patent. A true and complete copy of the '521 Patent is attached hereto as Exhibit P.

178. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '521 Patent.

179. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '521 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

180. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '521 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '521 Patent.

181. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in

ANDA No. 205616 would actively induce and contribute to infringement of the '521 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

182. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '521 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

183. DRL gave written notice of its certification of invalidity and/or non-infringement of the '521 Patent, alleging that claims of the '521 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '521 Patent.

184. DRL has infringed the '521 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '521 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '521 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

185. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '521 Patent. Plaintiffs do not have an adequate remedy at law.

Count XVI: Patent Infringement of the '594 Patent

186. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 185 above.

187. United States Patent No. 8,617,594, entitled "STABLE PHARMACEUTICAL COMPOSITION AND METHODS OF USING SAME," was duly and legally issued by the United States Patent and Trademark Office on December 31, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '594 Patent. A true and complete copy of the '594 Patent is attached hereto as Exhibit Q.

188. Upon information and belief, DRL submitted ANDA No. 205616 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '594 Patent.

189. DRL's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

190. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in DRL's ANDA No. 205616 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '594 Patent. Upon information and belief, this infringement will occur at DRL's behest, with its intent, knowledge, and encouragement, and DRL will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '594 Patent.

191. DRL's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in

ANDA No. 205616 would actively induce and contribute to infringement of the '594 Patent, and DRL would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

192. Upon information and belief, as part of the ANDA filing, DRL purportedly provided written certification to FDA that the claims of the '594 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of DRL's generic version of VASCEPA®.

193. DRL gave written notice of its certification of invalidity and/or non-infringement of the '594 Patent, alleging that claims of the '594 Patent are invalid and that certain claims would not be infringed by DRL's generic version of VASCEPA®, and informing Plaintiffs that DRL seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '594 Patent.

194. DRL has infringed the '594 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205616 with a paragraph IV certification and seeking FDA approval of ANDA No. 205616 to market a generic version of VASCEPA® prior to the expiration of the '594 Patent. Moreover, if DRL commercially uses, offers for sale, or sells its generic version of VASCEPA®, or induces or contributes to such conduct, it would further infringe the '594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

195. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing or contributing to infringement of the '594 Patent. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that DRL has infringed the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '225, '929, '698, '372, '521, and '594 Patents under 35 U.S.C. § 271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 205616 is not earlier than the expiration date of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '225, '929, '698, '372, '521, and '594 Patents, or any later expiration of exclusivity for the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '225, '929, '698, '372, '521, and '594 Patents to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining DRL and its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '225, '929, '698, '372, '521, and '594 Patents, including the product described in ANDA No. 205616;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 205616, or inducing or contributing to such conduct, would constitute infringement of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '225, '929, '698, '372, '521, and '594 Patents by DRL pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

Dated: April 30, 2014

Respectfully submitted,

/s/ Leda Dunn Wettre

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify that the same product and patents at issue in this action are the subject of two other actions currently pending in this District, captioned *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, Civ. A. No. 14-2550 (MLC) (DEA) (D.N.J) and *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc.*, Civ. A. No. 14-2551 (MLC) (DEA) (D.N.J).

Dated: April 30, 2014

Respectfully submitted,

By: */s/ Leda Dunn Wettre*

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